

DEPARTMENT OF HEALTH & HUMAN SERVICES**Public Health Service**

Office of Orphan Products Development(HF-35)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

January 12, 1994

RECEIVED JAN 18 1994

Therapeutic Antibodies, Inc.
Attention: Mr. John S. Cipriano, M.S. R.Ph.
Vice President Regulatory Affairs and Compliance
1500 21st Avenue South, Suite 310
Nashville, TN 37212

Dear Mr. Cipriano:

Reference is made to your orphan drug application of November 30, 1993 submitted pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act for the designation of CroTAb™ (polyvalent crotalid antivenin, ovine, Fab) as an orphan drug (application #93-789).

We have completed the review of this application and have determined that polyvalent crotalid antivenin, ovine, Fab qualifies for orphan designation for the treatment of envenomations inflicted by North American crotalid snakes. Please note that it is polyvalent crotalid antivenin, ovine, Fab and not its formulation that has received orphan designation.

Prior to marketing approval, sponsors of designated orphan products are requested to submit written notification to this Office of their intention to exercise orphan drug exclusivity if they are the first sponsor to obtain such approval for the drug. This notification will assist FDA in assuring that approval for the marketing of the same drug is not granted to another firm for the statutory period of exclusivity. Also please be advised that if polyvalent crotalid antivenin, ovine, Fab were approved for an indication broader than the orphan designation, your product might not be entitled to exclusive marketing rights pursuant to Section 527 of the FFDCA. Therefore, prior to final marketing approval, sponsors of designated orphan products are requested to compare the designated orphan indication with the proposed marketing indication and to submit additional data to amend their orphan designation prior to marketing approval if warranted.

In addition, please inform this office annually as to the status of the development program, and at such time as a marketing application is submitted to the FDA for the use of polyvalent crotalid antivenin, ovine, Fab as designated. If you need further assistance in the development of your product for marketing, please feel free to contact Mr. Peter Vaccari at (301) 443-4718.

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Please refer to this letter as official notification of designation and congratulations on obtaining your orphan drug designation.

Sincerely yours,

Marlene E. Haffner
Marlene E. Haffner, M.D., M.P.H.
Director



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

26 Jan

A. J. Kazimi
Chief Operating Officer
Therapeutic Antibodies, Inc.
1500 21st Avenue South, Suite 310
Nashville, TN 37212

Reference: FD-R-000945-01-1

CONFIDENTIAL

Dear Mr. Kazimi:

Enclosed is a revised Notice of Grant Award (NGA) for the above referenced grant project entitled "Clinical Trial of Polyspecific Crotalid Antivenin." Based on the justification provided in your letter dated October 28, 1993, all Special Terms and Conditions have been lifted.

PHS policy requires that you be informed that the DHHS Inspector General maintains a toll free telephone number (800/368-5779) for receiving information concerning fraud, waste and abuse under grants and cooperative agreements. Such reports will be kept confidential and callers may decline to give their names if they choose to remain anonymous.

If you have any questions concerning this action, please contact Ms. Maura Stephanos at (301) 443-6170.

Sincerely yours,

Robert L. Robins
Chief, Grants and Assistance
Agreements Section, SCAAB, DCGM

Enclosure

cc: Dr. Richard Dart, Principal Investigator
Rocky Mountain Poison Center
645 Bannock Street
Denver, CO 80204

1. DATE ISSUED (Mo./Day/Year) 07/20/1993

2. CFDA NO.

93.103

3. SUPERSEDES AWARD NOTICE dated 9/29/93 except that any additions or restrictions previously imposed remain in effect unless specifically rescinded.

4. GRANT NO. FD-R-000945-01-1

5. ADMINISTRATIVE CODES

FD-R01-6-O

Formerly:

6. PROJECT PERIOD Mo./Day/Yr. Mo./Day/Yr.

From 9/30/93 Through 9/29/94

7. BUDGET PERIOD Mo./Day/Yr. Mo./Day/Yr.

From 9/30/93 Through 9/29/94

8. TITLE OF PROJECT (OR PROGRAM) (Limit to 56 spaces)

Clinical Trial of Polyspecific Crotalid Antivenin

9. GRANTEE NAME AND ADDRESS

a. Therapeutic Antibodies, Inc.

b.
c. 1500 21st Avenue South, Suite 310
d. Nashville TN 37212

11. APPROVED BUDGET (Excludes PHS Direct Assistance)

I
I. PHS Grant Funds Only
II. Total project costs including grant funds and all other financial participation
(Select one and place NUMERAL in box.)

a. Salaries and Wages	\$ 24,550
b. Fringe Benefits	\$ 5,072
c. Total Personnel Costs	\$ 29,622
d. Consultant Costs	\$ 0
e. Equipment	\$ 0
f. Supplies	\$ 0
g. Travel	\$ 10,000
h. Patient Care—Inpatient	\$ 0
i. —Outpatient	\$ 0
j. Alterations and Renovations	\$ 0
k. Other	\$ 0
l. Consortium/Contractual Costs	\$ 59,800
m. Trainee Related Expenses	\$ 0
n. Trainee Stipends	\$ 0
o. Trainee Tuition and Fees	\$ 0
p. Trainee Travel	\$ 0
q. TOTAL DIRECT COSTS →	\$ 99,422
r. INDIRECT COSTS (Rate 0 % of S&W/TADC)	\$ 0
s. TOTAL APPROVED BUDGET	\$ 99,422
t. SBIR Fee	\$ 0
u. Federal Share	\$ 99,422
v. Non-Federal Share	\$ 0

12. AWARD COMPUTATION FOR FINANCIAL ASSISTANCE

a. Amount of PHS Financial Assistance (from Item 11.u.).....	\$ 99,422
b. Less Unobligated Balance From Prior Budget Periods.....	\$
c. Less Cumulative Prior Award(s) This Budget Period.....	\$ 99,422
d. AMOUNT OF FINANCIAL ASSISTANCE THIS ACTION.....	\$

13. RECOMMENDED FUTURE SUPPORT (SUBJECT TO THE AVAILABILITY OF FUNDS AND SATISFACTORY PROGRESS OF THE PROJECT):

YEAR	TOTAL DIRECT COSTS / STIPENDS	YEAR	TOTAL DIRECT COSTS / STIPENDS
a. 02	\$0	d.	
b.		e.	
c.		f.	

14. APPROVED DIRECT ASSISTANCE BUDGET (IN LIEU OF CASH):

a. Amount of PHS Financial Assistance.....	\$
b. Less Unobligated Balance From Prior Budget Periods.....	\$
c. Less Cumulative Prior Award(s) This Budget Period.....	\$
d. AMOUNT OF FINANCIAL ASSISTANCE THIS ACTION.....	\$

15. PROGRAM INCOME SUBJECT TO 45 CFR PART 74, SUBPART F, OR 45 CFR 92.25, SHALL BE USED IN ACCORD WITH ONE OF THE FOLLOWING ALTERNATIVES: (Select One and Place LETTER in box.)

- a. DEDUCTION
- b. ADDITIONAL COSTS
- c. MATCHING
- d. OTHER RESEARCH (Add / Deduct Option)
- e. OTHER (See REMARKS)

16. THIS AWARD IS BASED ON AN APPLICATION SUBMITTED TO, AND AS APPROVED BY, THE PHS ON THE ABOVE TITLE PROJECT AND IS SUBJECT TO THE TERMS AND CONDITIONS INCORPORATED EITHER DIRECTLY OR BY REFERENCE IN THE FOLLOWING:

- a. The grant program legislation cited above.
- b. The grant program regulation cited above.
- c. This award notice including terms and conditions, if any, noted below under REMARKS.
- d. PHS Grants Policy Statement including addends in effect as of the beginning date of the budget period
- e. 45 CFR Part 74 or 45 CFR Part 92 as applicable.

In the event there are conflicting or otherwise inconsistent policies applicable to the grant, the above order of precedence shall prevail. Acceptance of the grant terms and conditions is acknowledged by the grantee when funds are drawn or otherwise obtained from the grant payment system.

REMARKS: (Other Terms and Conditions Attached - Yes No)

This revised award is issued to list all Special Terms and Conditions.

PHS GRANTS MANAGEMENT OFFICER: (Signature)

R. L. Robins

(Name-Typed/Print)

(Title)

Robert L. Robins, Grants Management Officer

17. OBJ. CLASS.

41.41

18. CRS - EIN

1621212485A1

19. LIST NO.:

ID-17-94

FY-CAN

DOCUMENT NO.

ADMINISTRATIVE CODE

AMT. ACTION FIN. ASST.

AMT. ACTION DIR. ASST.

20. a. 3-6990114-W-1965

b. Appro. 7530600

c. FDR01

d. \$0

e. \$0

21. a.

b. PMS #22320Q-10

c.

d.

e.

22. a.

b. 06-000000945A

c.

d.

e.

GRANT PAYMENT INFORMATION
NOTE APPROPRIATE PAYMENT SYSTEM CHECKED BELOW

1. (X) Payments under this award will be made available through the DHHS Payment Management System (PMS). PMS is administered by the Division of Payment Management (DPM), Office of the Deputy Assistant Secretary, Finance, which will forward instructions for obtaining payments. Inquiries regarding payments should be directed to:

Division of Payment Management
DHHS/PHS/OASH/OM/ORM/DPM
P.O. Box 6021
Rockville, MD 20852
Telephone Number: (301) 443-1660

2. () Payments under this award will be made available through the Accounting and Indirect Cost Section, Federal Assistance Accounting Branch of the National Institutes of Health. Inquiries regarding payment should be directed to:

Accounting and Indirect Cost Section
Federal Assistance Accounting Branch
National Institutes of Health
Building 31, Room B1B04
9000 Rockville Pike
Bethesda, MD 20892
Telephone Number: (301) 496-5635

3. () Payments under this award will be made available through the Grants Section, General Accounting Branch of the Health Resources and Services Administration. Inquiries regarding payment should be directed to:

Grants Section, General Accounting Branch
Health Resources and Services Administration
Parklawn Building, Room 16-23
5600 Fishers Lane
Rockville, MD 20857
Telephone Number: (301) 443-1464

4. ()

The HHS Inspector General maintains a toll-free hotline for receiving information concerning fraud, waste, or abuse under grants and cooperative agreements. Such reports are kept confidential and callers may decline to give their names if they choose to remain anonymous. The numbers are:

(If caller is inside Maryland) 1-800-638-3986
(If caller is outside of Maryland) 1-800-368-5779

The mailing address is:

HHS, OIG Hotline
P.O. Box 17303
Baltimore, MD 21203-7303

NOTICE OF GRANT AWARD (Continuation Sheet)

PAGE	DATE ISSUED (Mo./Day/Yr.)
2 of 2	UV 26 Jan
GRANT NO.	FD-R-000945-01-1

ITEM NO.

TERMS AND CONDITIONS:**Reporting Requirements**

1. Quarterly program monitoring will be conducted which may be in the form of telephone conversations between the Principal Investigator and the Project Officer/Grants Management Specialist. Program monitoring may also be in the form of site visits.
2. Financial Status Reports (SF-269) and Program Progress Reports are required quarterly accordingly to the following schedule:

Quarter	Reporting Period	Reports Due
1st	10/01/93-12/31/93	01/31/94
2nd	01/01/94-03/31/94	04/30/94
3rd	04/01/94-06/30/94	07/31/94
4th	07/01/94-09/29/94	10/31/94

A Final Financial Status Report, Final Program Progress Report and an Invention Statement are due 12/31/94. These forms will be mailed to the Principal Investigator by the Grants Management Specialist.

An original and two copies of these reports must be submitted to the FDA Grants Management Officer by the due dates.

SPECIAL TERMS AND CONDITIONS:

1. This term and condition is lifted.
2. This term and condition is lifted.
3. This term and condition is lifted